UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA

ADAM F. GOLDBERG, individually and on behalf of himself and all others similarly situated, Plaintiff, vs. KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA LLC, Defendants.	**Case No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff Adam F. Goldberg ("Plaintiff"), individually and on behalf of all others similarly situated, for his complaint against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), and Philips RS North America LLC ("Philips RS") (collectively, Royal Philips, Philips NA, and Philips RS are "Philips" or the "Defendants"), alleges the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

I. NATURE OF THE ACTION

1. Defendants manufacture and sell a variety of products that are intended to assist people with breathing. These include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("Bi-Level PAP") machines that are commonly used to treat sleep apnea, and mechanical ventilators that treat respiratory failure. In general, each of these devices express air into patients' airways. CPAP and Bi-Level PAP machines are intended for daily use, and ventilators are used continuously while needed. These devices are designed to provide medical benefits to those who purchase and use them.

2. On April 26, 2021, Philips made a public announcement disclosing it had determined there were risks that the polyester-based polyurethane foam ("PE-PUR Foam") used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices it manufactured may degrade or off-gas under certain circumstances.

3. On June 14, 2021, Royal Philips issued a recall in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam,[1] because Philips had determined that (a) the PE-PUR Foam was at risk for degradation into particles that may enter the devices' pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain chemicals during operation.[2] Specifically, the PE-PUR Foam may emit volatile organic compounds ("VOCs") that are carcinogenic and may adversely affect organs if inhaled or ingested. Philips further disclosed in its Recall Notice that "these issues can result in serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."[3]

4. The use of a polyester-based polyurethane by Philips for its breathing machines was an unsuitable choice of material for the application.

5. Polyurethane is a polymer composed of organic units joined by carbamate (urethane) links. Polyurethanes are produced by reacting an isocyanate containing two or more isocyanate groups per molecule ($R-(N=C=O)_n$) with a polyol containing on average two or more hydroxyl (O-H) groups per molecule in the presence of a catalyst or by activation with ultraviolet

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[1] These include the following models: E30; DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C Series ASV, S/T, AVAPs; OmniLab Advanced Plus; SystemOne (Q Series); DreamStation CPAP, Auto CPAP, BiPAP; DreamStation Go CPAP, APAP; Dorma 400, 500 CPAP; REMStar SE Auto CPAP; Trilogy 100 and 200; Garbin Plus, Aeris, LifeVent; A-Series BiPAP Hybrid A30; A-Series BiPAP V30 Auto; A-Series BiPAP A40; and A-Series BiPAP A30 (collectively, "Recalled Devices").

[2] *See* Philips Recall Notice attached hereto as Exhibit "A."

[3] *Id.*

light.

6. The health effects of isocyanate exposure include, among other things, irritation of skin and mucous membranes, chest tightness, and difficult breathing. Isocyanates include compounds classified as potential human carcinogens and known to cause cancer in animals. The additional known hazardous effects of isocyanate exposures are occupational asthma and other lung problems, as well as irritation of the eyes, nose, throat, and skin.

7. Polyurethanes, especially those made using aromatic isocyanates, contain chromophores that interact with light. When polyurethane foam, which is made using aromatic isocyanates, is exposed to visible light, it discolors, turning off-white to yellow to reddish brown, and finally to black.

8. Degradation of polyurethane can result in the material becoming hard and friable, which can cause particles to be propelled by air movement. Degradation of the polyester polyurethane into volatile components (which may include hydrogen cyanide, and other toxic components) which can be ingested into the airways, absorbed on skin and tissue, or into the bloodstream. If depolymerization of the urethane occurs, isocyanate can evolve, which is toxic and potentially carcinogenic. Additionally, amines, glycols, and phosphate may produce additional risks.

9. Philips' ventilators and CPAP/Bi-Level PAP machines are used in a high-humidity, elevated-temperature (95-110°F) application complicated by the presence of bacteria and potential fungal growth. Polyester polyurethane is particularly sensitive to degradation from heat, oxygen (ozone), sunlight (ultraviolet), moisture, microbial, and fungal attack. The properties of polyester polyurethanes have been well known and have been well documented and readily available in the scientific literature for many years well before Philips started manufacturing the Recalled Devices.

10. The selection of polyester polyurethane by Philips for application in its ventilator

and CPAP/Bi-Level PAP machines was highly inappropriate in that it breached the relevant standard of care because all of health and safety risks set forth in the recall were known before the sale of any of the Recalled Devices and imminently foreseeable, all the while safe alternatives were available.

11. Furthermore, Philips knew or should have known about these very substantial and material health risks associated with the degradation of polyester polyurethane before any of these machines were sold and nonetheless used the material because it was expedient. In so doing, Defendants knowingly subordinated the health interests of their customers to their own financial gain.

12. Defendants now report in the recall that "based on testing there are possible risks to users related to this type of foam," and that "Philips has received reports of possible patient impact due to foam degradation."

13. Plaintiff is informed and believes that these "risks" and certainty of degradation were known before any of the Recalled Devices were sold, because the properties of polyester polyurethane and likelihood of degradation in this application were known to the industry, were common knowledge to polymer experts and were readily available and known to Defendants before the machines went to market.

14. In that context, Defendants defrauded Plaintiff and the Class and Subclass at the time and place of each sale by failing to disclose the risk of harm – risks which were known or should have been known before the Recalled Devices were sold. Defendants' awareness of the properties of polyester polyurethane in this application, namely, high temperature, high moisture and susceptibility for fungi and microbes would lead to degradation and the inevitable and known health risks, required that Defendants disclose these risks before every sale of the products.

15. No one would have purchased, leased or used these products had the Defendants

disclosed the health risks before each sale.

16. The failure to disclose the known risks also constituted an unfair business practice in that it was unfair and fraudulent to consumers and uniformly impacted and damaged Plaintiff and all Class and Subclass members who would not have otherwise purchased, leased or used the Recalled Devices.

17. Similarly, the universal warranty promise from Defendants that the Recalled Devices would be "free from defects of workmanship and materials" was false, misleading and unlawful in that Defendants breached the warranties, express and implied, by so warrantying these products.

18. Consumers who use the Recalled Devices have complained about black particles in their machines for several years. Philips, however, did not warn the public or its customers about these hazards until late April 2021, and did not recall the Recalled Devices until June 14, 2021.

19. Philips has no concrete timeline for replacing or repairing any of the Recalled Devices.

20. The recall of the Recalled Devices coincided with the launch of Defendants' next generation of products, which purportedly do not suffer from the same PE-PUR Foam issues. An option that Philips offers to its customers—many of whom need and rely on the Recalled Devices—is to purchase or lease a newer model, thus further profiting from its own wrongdoing.

21. Plaintiff brings this Class Action Complaint to represent a class and subclass of similarly situated persons defined below, who purchased, leased, or used the defective Recalled Devices, and to obtain damages for the cost of replacement of the machines and/or repair, assuming repair is possible, and for medical monitoring for users of Philips' devices identified in the Recall Notice, who are at risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*,

kidneys and liver) and toxic carcinogenic effects.

II. PARTIES

A. PLAINTIFF

22. Plaintiff Adam F. Goldberg resides in Los Angeles, California. He was diagnosed with sleep apnea and purchased a DreamStation Bi-Level PAP machine in 2009 at a cost of approximately $697. He subsequently purchased a DreamStation Auto CPAP Hum WiFi DOM machine in 2017 at a cost of approximately $1,646.25. His use of the DreamStation devices was prescribed by his physician. He would not have purchased these products if he had known they were defective and included an unsuitable polyurethane foam which exudes a potentially carcinogenic by-product and other material hazardous to his health. Plaintiff further avers that he has, since using the DreamStation Recalled Devices, developed asthma and chronic sinus migraines, both of which he attributes to his use of the Recalled Devices. To date, Defendants have failed to replace or repair his machine, or to provide any assistance. Because of the recall, Plaintiff has been forced to purchase an expensive replacement machine known as the ResMed AirCurve 10 VAuto BiLevel / Bi-Level PAP Machine with HumidAir Heated Humidifier and associated headgear at a cost of $2,468. The ResMed AirCurve was ordered on September 3, 2021. The use of a breathing machine is necessary for his health given his medical condition. Plaintiff demands a refund and all other appropriate economic damages he has or will incur, and compensation for what he has suffered or will suffer as a result of purchasing and using his defective DreamStation devices.

B. DEFENDANTS

23. Defendant Royal Philips is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including Connected Care businesses focusing

on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips NA and Philips RS.[4] Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing, and supplying of the recalled CPAP, Bi-Level PAP, and mechanical ventilator devices.[5]

24. Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips.

25. Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly-owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.[6]

26. Reference to "Philips," "Defendant," or "Defendants" refers to each and every Defendant individually and collectively.

III. JURISDICTION AND VENUE

27. This Court has subject-matter jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (1) the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, (2) the action is a class action, (3) there are members of the Class and Subclass who are diverse from Defendants, and (4) there are more than 100 class

[4] Philips 2020 annual filing with the SEC, fn. 8, https://www.sec.gov/Archives/edgar/data/313216/000031321621000008/phg-exhibit8.htm (accessed June 30, 2021).

[5] Philips 2020 annual filing with the SEC, https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm (accessed June 30, 2021).

[6] Philips announces completion of tender offer to acquire Respironics, WEB WIRE, https://www.webwire.com/ViewPressRel.asp?aId=61199 (accessed June 27, 2021).

members. This Court has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367, because they form part of the same case or controversy as the claims within the Court's original jurisdiction.

28. This Court has personal jurisdiction over the Defendants because Defendants conduct substantial business in this District, and the events giving rise to Plaintiff's claims arise out of and relate to Defendants' contacts with this District. Moreover, Defendant Philips RS has its principal place of business in the forum State. Defendants Philips RS and Philips NA are controlled by their parent Royal Philips. Defendants' affiliations with this District are so continuous and systematic as to render them essentially at home in the forum State. Further, Defendants have transacted business, maintained substantial contacts, purposefully targeted consumers and medical professionals for sales of its devices and/or committed overt acts in furtherance of the unlawful acts alleged in this Complaint in this District, as well as throughout the United States. The unlawful acts of Defendants have been directed at, targeted, and have had the effect of causing injury to persons residing in, located in, or doing business in this District, as well as throughout the United States.

29. Venue is proper in this District because Defendants conduct substantial business in this District, a substantial part of the events or omissions giving rise to the claim occurred in this District, and Defendants caused harm to Class members residing in this District.

IV. FACTUAL ALLEGATIONS

A. CPAP MACHINES, BI-LEVEL PAP MACHINES, AND VENTILATORS TREAT SERIOUS CONDITIONS.

30. Sleep apnea is a sleeping disorder in which breathing is disturbed temporarily during sleep. Breathing may stop or become very shallow. This may be associated with fatigue, daytime sleepiness, interrupted sleep, or snoring, among other symptoms. Serious cases can lead to hypertension, heart attack, or stroke, among other medical ailments.

31. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose and/or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea.

32. Other therapies to treat sleep apnea include Bi-Level PAP therapy and Automatic Positive Airway Pressure ("APAP"). Bi-Level PAP machines provide two different pressure settings, one for inhalation and one for exhalation.

33. Patients who use CPAP or Bi-Level PAP machines typically use them every day when they sleep. Symptoms may return quickly if therapy is discontinued.

34. Respiratory failure is a condition in which a patient has difficulty breathing or getting enough oxygen into the blood. Many underlying conditions can cause respiratory failure, including physical trauma, sepsis, pneumonia, COVID-19, and drug abuse. Respiratory failure can be fatal.

35. Mechanical ventilators, usually called "ventilators," are often used to treat respiratory failure. Ventilators push air into and out of the patient's lungs like a bellows. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. The COVID-19 crisis has led to a significant increase in the demand for ventilators in California, the United States and worldwide.

B. PHILIPS RECALLED ITS PRODUCTS DUE TO SERIOUS HEALTH HAZARDS FROM THE FOAM THAT IT UTILIZED.

36. Philips manufactures and sells CPAP machines, Bi-Level PAP machines, and ventilators, among other products. According to Philips' 2020 Annual Report, Sleep & Respiratory Care constituted approximately 49% of Philips's total sales in its Connected Care line of business, which in turn accounted for 28% of Philips's overall sales of about €19.535 billion.

37. Philips' flagship CPAP/Bi-Level PAP machine product family is known as the "DreamStation" family line, which includes the original DreamStation, launched in October 2015, and the DreamStation Go (a travel version). Philips sells DreamStation products through its subsidiary Respironics, that Philips acquired in 2008.

38. Many of Philips' CPAP and Bi-Level PAP machines and ventilators contain PE-PUR Foam for sound abatement. By design of these machines, air passes through this foam before it is pumped into the patient's airway.

39. On April 13, 2021, Philips announced that it was launching the DreamStation 2, the next-generation machine in its DreamStation product family.

40. Less than two weeks later, on April 26, 2021, Philips announced the recall and, in the same release, shockingly started pushing consumers to purchase its latest generation device:

> Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone*), and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.

41. On June 14, 2021, Philips then issued a further statement:

> To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use

> of unapproved cleaning methods, such as ozone,** and high heat and high humidity environments may also contribute to foam degradation.
>
> Therefore, Philips has decided to voluntarily issue a recall notification* to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.

42. Philips stated that "[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family." Philips elaborated:

> Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification* advises patients and customers to take the following actions:
>
> For patients using affected BiLevel PAP and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.*
>
> For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.*
>
> **Possible health risks**
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> The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions.

43. On the same day, Philips provided additional information in an announcement entitled "Clinical information for physicians," which explained that the foam breakdown "may lead to patient harm and impact clinical care."

> While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.

44. The announcement by Philips detailed two types of hazards from the PE-PUR Foam in the devices. First, the announcement described dangers due to foam degradation exposure:

> **Potential Hazard:** Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.
>
> The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
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> - Toluene Diamine
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> - Toluene Diisocyanate
>
> - Diethylene glycol

45. The European Union considers Toluene Diisocyanate "highly toxic" and has concluded that Toluene Diamine "cannot be considered safe for use" even as a hair dye.

46. Philips disclosed that it "has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."

47. The second hazard is the possibility of VOCs, that is, chemical emissions from the PE-PUR foam. Philips explained:

> **Potential Hazard:** Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long term adverse health effects.
>
> Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:
>
> - Dimethyl Diazine
>
> - Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)

48. Philips admitted that the risks of these VOCs include that they "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects," as well as "adverse effects to other organs such as kidney and liver."

49. Although Philips did not disclose these health risks until June 2021, Philips has known about these health risks for a long time. For example, customers have complained to Philips about black particles in their machines for several years as evidenced by forum posts and statements from those that follow the industry. In addition, had Defendants conducted adequate research before selecting PE-PUR Foam for use in its Recalled Devices, they should have chosen an alternative material for the application.

C. PHILIPS HAS NO ACCEPTABLE PLAN TO REPLACE RECALLED DEVICES.

50. In a press release issued on September 1, 2021, Philips indicated it had received authorization from the FDA to "rework" recalled first-generation DreamStation CPAP devices, including the replacement of PE-PUR Foam in the Recalled Devices. However, it is unknown what the timeline for that process is. Further, it is unknown what Philips is doing with regard to replacement of the foam in the affected devices. And, it is unknown when, or if ever, Philips will be able to provide its customers with suitable devices.

51. There is also a general shortage of available replacement machines.

52. But patients need to use their machines every day, or else their symptoms—which can be severe and life-altering—may return.

53. As a result, the recall by Philips leaves patients without safe, free options. Patients may buy Philips' next-generation product or a competitor's product—at full price, if such products are available.

54. Pursuant to the statements issued by Philips that are set forth above, Philips has admitted that the Recalled Devices are defective and unsafe. The Recalled Devices are effectively worthless and/or have far less value than what customers paid and would not have been purchased by patients if they were informed of the defect at the time of sale.

55. Plaintiff and the Class and Subclass members have all suffered economic damages as a result of their purchase or lease of the Recalled Devices in an amount equal to the purchase or lease price of their Recalled Devices and/or the cost of a replacement machine.

V. CLASS ALLEGATIONS

56. Plaintiff brings this action individually and as a class action pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3). Specifically, the Classes that Plaintiff seeks to represent consists of the following:

> **NATIONWIDE CLASS**: All persons in the United States who purchased, leased or used a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was manufactured by Philips before April 26, 2021, and recalled by Philips on June 14, 2021.
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> **CALIFORNIA SUBCLASS**: All persons who were or are citizens of the State of California who purchased, leased or used a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was manufactured by Philips before April 26, 2021, and recalled by Philips on June 14, 2021.

57. Excluded from the Class and Subclass are: (a) any Judge or Magistrate Judge presiding over this action and members of their staff, as well as members of their families; (b) Defendants' and Defendants' predecessors, parents, successors, heirs, assigns, subsidiaries, and any entity in which any Defendants or their parents have a controlling interest, as well as Defendants' current or former employees, agents, officers, and directors; (c) persons who properly execute and file a timely request for exclusion from the Class or Subclass; (d) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (e) counsel for Plaintiff and Defendants; and (f) the legal representatives, successors, and assigns of any such excluded persons.

58. Plaintiff reserves the right to redefine the Class and Subclass prior to class certification.

59. The rights of each member of the Class and Subclass were violated in a similar fashion based upon Defendants' uniform actions.

60. This action has been brought and may be properly maintained as a class action for the following reasons:

61. **Numerosity (Rule 23(a)(1))**. The Class and Subclass are so numerous that joinder of individual members herein is impracticable. The exact number of members of the Class and Subclass, as herein identified and described, is not known, but sales figures and the Recall Notice indicate that millions of individuals have purchased the Recalled Devices.

62. **Commonality (Rule 23(a)(2))**. Common questions of fact and law exist for each cause of action and predominate over questions affecting only individual Class and Subclass members, including the following:

- whether Defendants owed a duty of care to Plaintiff and the Class and Subclass;
- whether Defendants knew or should have known that the PE-PUR Foam used for sound abatement posed health risks;
- whether Defendants wrongfully represented that the PE-PUR Foam used for sound abatement in the Recalled Devices was safe;
- whether the Recalled Devices retained any value post-recall;
- whether Defendants wrongfully represented that the Recalled Devices were safe to use;
- whether Defendants wrongfully failed to disclose that the PE-PUR Foam used for sound abatement in the Recalled Devices posed health risks to Recalled Device users;
- whether Defendants' representations and omissions in advertising, warranties, packaging, and/or labeling were false, deceptive, and/or misleading;
- whether those representations and omissions were likely to deceive a reasonable consumer;
- whether a reasonable consumer would consider the presence, or risk of, health risks as a material fact in purchasing one of the Recalled Devices;
- whether Defendants had knowledge that those representations and omissions were false, deceptive, and misleading;
- whether Defendants breached their express warranties;
- whether Defendants breached their implied warranties;

- whether Defendants engaged in unfair trade practices;
- whether Defendants engaged in false advertising;
- whether Defendants' conduct was negligent per se;
- whether Defendants made negligent and/or fraudulent misrepresentations and/or omissions;
- whether Defendants violated California's Unfair Competition Law, Bus. & Prof. Code § 17200 *et seq*., by, among other things, engaging in unfair, unlawful, or fraudulent practices;
- whether Defendants were unjustly enriched by the sale of the Recalled Devices;
- whether Plaintiff and the members of the Class and Subclass are entitled to actual, statutory, and punitive damages, and the amount of such damages; and
- whether Defendants should be declared financially responsible for the costs and expenses of the replacement of all Recalled Devices.

These and other questions of law or fact that are common to the members of the Class and Subclass predominate over any questions affecting only individual members of the Class.

63. **Typicality (Rule 23(a)(3))**. Plaintiff's claims are typical of the claims of the other members of the proposed Class and Subclass. Plaintiff and members of the Class and Subclass (as applicable) suffered injuries as a result of Defendants' wrongful conduct that is uniform across the Class and Subclass.

64. **Adequacy (Rule 23(a)(4))**. Plaintiff's interests are aligned with the Class and Subclass he seeks to represent. Plaintiff has and will continue to fairly and adequately represent and protect the interests of the Class and Subclass. Plaintiff has retained competent counsel highly experienced in complex litigation and class actions and the types of claims at issue in this litigation, with the necessary resources committed to protecting the interests of the Class and Subclass.

Plaintiff has no interest that is antagonistic to those of the Class and Subclass, and Defendants have no defenses unique to Plaintiff. Plaintiff and his counsel are committed to vigorously prosecuting this action on behalf of the members of the Class and Subclass. Neither Plaintiff nor Plaintiff's counsel have any interest adverse to those of the other members of the Class and Subclass.

65. **Superiority**. This class action is appropriate for certification because class proceedings are superior to other available methods for the fair and efficient adjudication of this controversy, and joinder of all members of the Class and Subclass is impracticable. The prosecution of separate actions by individual members of the Class and Subclass would impose heavy burdens upon the Courts and Defendants, would create a risk of inconsistent or varying adjudications of the questions of law and fact common to members of the Class and Subclass, and would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests. Class treatment will create economies of time, effort, and expense and promote uniform decision-making.

66. **Manageability.** This proposed class action presents fewer management difficulties than individual litigation, and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

67. Class certification, therefore, is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

VI. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

68. Plaintiff and the Class and Subclass had no way of knowing about Philips' conduct with respect to the health risks associated with the use of the Recalled Devices.

69. Neither Plaintiff nor any other members of the Class or Subclass, through the exercise of reasonable care, could have discovered the conduct by Philips alleged herein. Further, Plaintiff and members of the Class and Subclass did not discover and did not know of facts that would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged herein.

70. For these reasons, all applicable statutes of limitation have been tolled by the discovery rule with respect to claims asserted by Plaintiff, the Class, and Subclass.

VII. FRAUDULENT CONCEALMENT TOLLING OF STATUTES OF LIMITATIONS

71. By failing to provide immediate notice of the adverse health effects associated with continued use of the Recalled Devices, Philips concealed its conduct and the existence of the claims asserted herein from Plaintiff and the members of the Class and Subclass.

72. Upon information and belief, Philips intended its acts to conceal the facts and claims from Plaintiff and members of the Class and Subclass. Plaintiff and the members of the Class and Subclass were unaware of the facts alleged herein without any fault or lack of diligence on their part and could not have reasonably discovered Defendants' conduct. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiff or members of the Class or Subclass should be tolled.

VIII. CAUSES OF ACTION

COUNT I

DESIGN DEFECT STRICT LIABILITY
(on behalf of the Class or, alternatively, the Subclass)

73. Plaintiff and the Class and Subclass incorporate by reference all preceding paragraphs, as if fully set forth.

74. The design of the Recalled Devices, including, but not limited to, design and use of the PE-PUR Foam and the placement of the foam within the Recalled Devices, was defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR Foam, and exposure to materials with toxic and carcinogenic effects.

75. The design of the Recalled Devices and the PE-PUR Foam rendered the Recalled Devices not reasonably fit, suitable, or safe for their intended purpose.

76. The dangers of the Recalled Devices outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP, Bi-Level PAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions.

77. Safe, alternative machines from other manufacturers were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Devices and their unsafe PE-PUR Foam.

78. The risk benefit profile of the Recalled Devices was unreasonable, and should not have been sold in the market.

79. The Recalled Devices failed to perform in a safe manner as an ordinary consumer of the product would expect.

80. Plaintiff and the Class and Subclass suffered damages equal to the purchase or lease price of the machines, or the cost of replacing the machines and such other economic damages, the amount of which to be determined at trial.

81. As a direct and proximate result of their use of the Recalled Devices, Plaintiff and the Class and Subclass are at a substantially increased risk of developing serious medical conditions, including risk of suffering from serious injury, including irritation (skin, eye, and

respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

82. The latent injuries from which Plaintiff, Class, and Subclass members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to harmful chemicals from the degrading PE-PUR Foam and off-gassing VOCs, and is different from that normally recommended in the absence of exposure to this risk of harm.

83. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the aforementioned injuries.

84. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the aforementioned injuries.

85. By monitoring and testing Plaintiff, Class, and Subclass members, the risk that Plaintiff and the Class and Subclass members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

86. Plaintiff and the Class and Subclass members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the Class and Subclass members for the aforementioned injuries. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and the Class and Subclass members as frequently and appropriately as necessary.

87. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has used the Recalled Devices for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Class and Subclass members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

88. Plaintiff and the Class and Subclass have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to use of the Recalled Devices. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the Class and Subclass members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT II

NEGLIGENT DESIGN DEFECT
(on behalf of the Class or, alternatively, the Subclass)

89. Plaintiff and the Class and Subclass incorporate by reference all preceding paragraphs, as if fully set forth.

90. Defendants negligently designed the Recalled Devices. Philips owed Plaintiff and the Class and Subclass a duty to design the Recalled Devices in a reasonable manner. The design of the Recalled Devices, including but not limited to the design of the PE-PUR Foam and the placement of the PE-PUR Foam within the Recalled Devices, was defective and unreasonably dangerous, causing degradation and inhalation of the foam, and exposure to materials with toxic and carcinogenic effects.

91. The design of the Recalled Devices and the PE-PUR Foam rendered the Recalled Devices not reasonably fit, suitable, or safe for their intended purpose.

92. The dangers of the Recalled Devices outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are CPAP and Bi-Level PAP devices and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions.

93. Safer, alternative machines from other manufacturers were available that did not have an unreasonable risk of harm as with the Recalled Devices and their unsafe foam.

94. The risk benefit profile of the Recalled Devices was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.

95. The Recalled Devices failed to perform in a safe manner as an ordinary consumer would expect.

96. Plaintiff and the Class and Subclass suffered damages equal to the purchase or lease price of the machines, or the cost of replacing the machines and such other economic damages, the amount of which to be determined at trial.

97. As a direct and proximate result of their use of the Recalled Devices, Plaintiff and the Class and Subclass are at a substantially increased risk of developing serious medical conditions, including risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

98. The latent injuries from which Plaintiff, Class, and Subclass members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to harmful chemicals from the degrading PE-PUR Foam and off-gassing VOCs, and is different from that normally recommended in the absence of exposure to this risk of harm.

99. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the aforementioned injuries.

100. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the aforementioned injuries.

101. By monitoring and testing Plaintiff, Class, and Subclass members, the risk that Plaintiff and the Class and Subclass members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

102. Plaintiff and the Class and Subclass members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the Class and Subclass members for the aforementioned injuries. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Class and Subclass members as frequently and appropriately as necessary.

103. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has used the Recalled Devices for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Class and Subclass members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

104. Plaintiff and the Class and Subclass have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to use of the Recalled Devices. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the Class and Subclass members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT III

BREACH OF EXPRESS WARRANTY
(on behalf of the Class or, alternatively, the Subclass)

105. Plaintiff and the Class and Subclass incorporate by reference all preceding paragraphs, as if fully set forth herein.

106. Defendants warranted the Recalled Devices shall be free from defects of workmanship and materials and will perform in accordance with the product specifications.

107. Because Defendants were well aware of the defects in materials and failed to disclose the defects, Defendants are barred and estopped from asserting that warranty claims are barred based upon the warranty period. Plaintiff and all Class and Subclass members were unaware of the defects in materials and could not have reasonably learned or discovered of such defects.

108. Defendants breached the express warranty in that the Recalled Devices did not conform to the express description of the quality, characteristic or performance of the products, which were not reasonably suitable for the ordinary purposes for which they were used; and which did not reasonably conform to the promises made in the warranty. At the point of sale, the Recalled Devices while appearing normal—contained immediate defects as set forth herein, rendering them unsuitable, unfit and unsafe for the intended use by all users of the machines.

109. Had Plaintiff and the Class and Subclass known the Recalled Devices were unsafe for use, they would not have purchased, leased or used them. Before the recall, purchasers/consumers did not know of the dangerous condition of the machines but believed them

to be safe for its intended use, and used the product in a reasonable manner, appropriate for the purpose for which it was intended. When Plaintiff and the Class and Subclass used the machines, they had not been altered or modified, and no action by Plaintiff caused or contributed to the defect.

110. Defendants have breached their warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiff and the Class and Subclass reasonably expected, at the time of purchase, lease or use, that the Recalled Devices were safe for their ordinary and intended use.

111. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and the Class and Subclass suffered damages equal to the purchase or lease price of the machines, or the cost of replacing the machines and such other economic damages, the amount of which to be determined at trial.

112. As a direct and proximate result of their use of the Recalled Devices, Plaintiff and the Class and Subclass are at a substantially increased risk of developing serious medical conditions, including risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

113. The latent injuries from which Plaintiff, Class, and Subclass members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to harmful chemicals from the degrading PE-PUR Foam and off-gassing VOCs, and is different from that normally recommended in the absence of exposure to this risk of harm.

114. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma,

adverse effects to other organs (*e.g.*, kidneys and liver) and cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the aforementioned injuries.

115. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the aforementioned injuries.

116. By monitoring and testing Plaintiff, Class, and Subclass members, the risk that Plaintiff and the Class and Subclass members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

117. Plaintiff and the Class and Subclass members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the Class and Subclass members for the aforementioned injuries. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Class and Subclass members as frequently and appropriately as necessary.

118. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has used the Recalled Devices for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Class and Subclass members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

119. Plaintiff and the Class and Subclass have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to use of the Recalled Devices. Without a court-approved medical monitoring program

as described herein, or established by the Court, Plaintiff and the Class and Subclass members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT IV

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY (on behalf of the Class or, alternatively, the Subclass)

120. Plaintiff and the Class and Subclass incorporate by reference all preceding paragraphs, as if fully set forth.

121. By operation of law, Defendants, as manufacturers of the Recalled Devices and as the providers of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiff and the Class and Subclass that the Recalled Devices were of merchantable quality and safe for their ordinary and intended use.

122. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices while appearing normal—contained defects as set forth herein rendering them unsuitable and unsafe for personal use by consumers and users of the machines. When Plaintiff and the Class and Subclass used the machines, they had not been altered or modified, an no action by Plaintiff caused or contributed to the defect.

123. Had Plaintiff and the Class and Subclass known the Recalled Devices were unsafe for use, they would not have purchased, leased or used them. Before the recall, purchasers/consumers did not know of the dangerous condition of the machines but believed them to be safe for its intended use, and used the products in a reasonable manner, appropriate for the purpose for which they were intended.

124. Defendants have refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiff and the Class and Subclass reasonably expected, at the time of purchase, that the Recalled Devices were safe for their ordinary and intended use.

125. Defendants issued the warranty to Plaintiff and the Class and Subclass. Defendants extended the benefit of the express warranty to Plaintiff and members of the Class and Subclass. Defendants are therefore in direct privity with each Plaintiff and all members of the Class and Subclass.

126. Further, the implied warranties incorporated into the transaction between Defendants and its immediate purchasers and lessees (the "Philips Buyers"), which were distributors of the Recalled Devices, were intended solely to benefit Plaintiff and the Class and Subclass. Plaintiff and the Class and Subclass are therefore entitled to enforce the implied warranties against Defendants.

127. Further, the implied warranties made by Defendants to the Philips Buyers would be of no economic value to the Philips Buyers unless Plaintiff and Class and Subclass received the benefit of such warranties. The Philips Buyers are not users of the Recalled Devices. The economic benefit of implied warranties made by Defendants to the Philips Buyers depends on the ability of end users who buy or lease their products to obtain redress from Defendants if the warranties are breached.

128. Under *Gilbert Financial Corp. v. Steelform Contracting Co.* (1978) 82 Cal. App. 3d 65, the implied warranties made by Defendants to Plaintiff and the Class and Subclass are enforceable whether or not Plaintiff or the Class and Subclass were in privity of contract with Defendants.

129. Defendants breached the implied warranties in that the Recalled Devices are: (1) not fit for their intended use and (2) not of merchantable quality. The Recalled Devices are neither merchantable nor fit for their intended use because: (1) the latent defect in the Recalled Devices insures that they are unsafe and will fail well before the end of their useful life; and (2)

purchasers and lessees of the Recalled Devices would not accept the health risks posed by the Recalled Devices when there are other products for sale which do not present these health risks.

130. Although Plaintiff does not believe that notice to Defendants of their breaches of warranty are required under applicable law, notice to Defendants of their breach of the implied warranties would be futile because Defendants are aware of and have acknowledged and admitted the defects in the Recalled Devices in the recall and because they cannot provide to Plaintiff and the Class and Subclass any remedy other than replacement of the Recalled Devices, which they have not provided, or cure the defect, or pay the cost to purchase comparable non-defective machines.

131. Because the Recalled Devices have failed and pose serious health risks within their expected useful life, Defendants are in breach of the warranty. Harm to Plaintiff and the Class and Subclass is detailed hereinabove.

132. As detailed herein, Defendants have failed to remedy the breach of the warranty for either Plaintiff or the Class and Subclass.

133. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff and the Class and Subclass suffered damages equal to the purchase or lease price of the machines, or the cost of replacing the machines and such other economic damages, the amount of which to be determined at trial.

134. As a direct and proximate result of their use of the Recalled Devices, Plaintiff and the Class and Subclass are at a substantially increased risk of developing serious medical conditions, including risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

135. The latent injuries from which Plaintiff, Class, and Subclass members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to harmful chemicals from the degrading PE-PUR Foam and off-gassing VOCs, and is different from that normally recommended in the absence of exposure to this risk of harm.

136. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the aforementioned injuries.

137. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the aforementioned injuries.

138. By monitoring and testing Plaintiff, Class, and Subclass members, the risk that Plaintiff and the Class and Subclass members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

139. Plaintiff and the Class and Subclass members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the Class and Subclass members for the aforementioned injuries. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Class and Subclass members as frequently and appropriately as necessary.

140. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who has used the Recalled Devices for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Class and Subclass members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

141. Plaintiff and the Class and Subclass have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to use of the Recalled Devices. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the Class and Subclass members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT V

FOR VIOLATION OF UNFAIR COMPETITION LAW
(on behalf of the Class, or alternatively, the Subclass, except for Class Members who purchased a Recalled Device for business use only)

142. Plaintiff and the Class and Subclass incorporate by reference all preceding paragraphs, as if fully set forth herein.

143. Pursuant to Bus. & Prof. Code § 17200, "unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising."

144. Defendants' actions, as alleged herein, constitute deceptive, unfair, fraudulent, and unlawful practices committed in violation of the Bus. & Prof. Code § 17200, *et seq*.

145. All of the conduct and representations alleged herein occurred in the course of the Defendants' business and were part of a pattern or generalized course of conduct.

146. The Defendants' conduct was **unlawful**.

147. The advertising and sale of the Recalled Devices by use of warranty documents was **fraudulent** because it was likely to and did deceive purchasers into believing that the Recalled

Devices would be free from defects and provide safe and reliable breathing assistance. The Recalled Devices are not free from defects or safe and pose dangerous and unnecessary health hazards to Plaintiff and Class and Subclass members. Defendants' omission to disclose the facts it was required to disclose is also **fraudulent** under Bus. & Prof. Code § 17200 in that Defendants have long been aware of all defects that are the basis of the recall and failed to disclose those defects and health hazards to Plaintiff and the Class and Subclass. The supporting allegations are detailed above.

148. Defendants' deceptive, fraudulent, unfair, and unlawful conduct alleged herein was specifically designed to and did induce Plaintiff and members of the Class and Subclass to purchase, lease or use the Recalled Devices.

149. Plaintiff and members of the Class and Subclass reasonably and justifiably relied on Defendants' deceptive, fraudulent, unfair, and unlawful conduct alleged herein. But for such conduct, Plaintiff and members of the Class and Subclass would not have purchased, leased or used the Recalled Devices.

150. As a result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and members of the Class and Subclass have suffered injury-in-fact, lost money, and lost property, in that they have incurred out-of-pocket costs and loss associated with the faulty Recalled Devices, as described more fully herein.

151. Pursuant to Bus. & Prof. Code §§ 17203, 17204, Plaintiff and the Class and Subclass seek to recover from Defendants restitution of earnings, profits, compensation and benefit obtained as a result of the practices that are unlawful under Bus. & Prof. Code § 17200 *et seq.*, and other appropriate relief, according to proof.

152. Additionally, by failing to provide safe replacement machines and by understating and failing to disclose the health risk resulting from the failure of the Recalled Devices, Defendants

acted unfairly and unlawfully breached all warranties as alleged herein against all members of the Class and Subclass. Members of the Class and Subclass have been damaged and will continue to be damaged by the breaches of the warranty and the failure to disclose the risk of harm posed by the Recalled Devices.

153. The above alleged acts are **unfair** in that they: (1) violate public policy as expressed in the Song-Beverly Consumer Warranty action; (2) are immoral, unethical, oppressive, unscrupulous and substantially injurious to consumers for failing to timely disclose to Plaintiff and the Class and Subclass the known and foreseeable harmful effects of polyester polyurethane when used in the Recalled Devices, all of which were known to Defendants before and after the machines were purchased or leased. These factors are not offset by the utility of Defendants' conduct since the conduct is intended to and does only provide impediments to the assertion of valid claims for recovery and limit the damages which Defendants are legally obligated to compensate; and (3) inflict substantial injury on consumers which is not outweighed by any countervailing benefits to consumers or competition and the injury to consumers is one consumers could reasonably have avoided.

154. As a direct and proximate result of their use of the Recalled Devices, Plaintiff and the Class and Subclass are at a substantially increased risk of developing serious medical conditions, including risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

155. The latent injuries from which Plaintiff, Class, and Subclass members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to harmful chemicals from the

degrading PE-PUR Foam and off-gassing VOCs, and is different from that normally recommended in the absence of exposure to this risk of harm.

156. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the aforementioned injuries.

157. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the aforementioned injuries.

158. By monitoring and testing Plaintiff, Class, and Subclass members, the risk that Plaintiff and the Class and Subclass members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

159. Plaintiff and the Class and Subclass members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the Class and Subclass members for the aforementioned injuries. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Class and Subclass members as frequently and appropriately as necessary.

160. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has used the Recalled Devices for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Class

and Subclass members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

161. Plaintiff and the Class and Subclass have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to use of the Recalled Devices. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the Class and Subclass members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT VI

UNJUST ENRICHMENT
(on behalf of the Class, or alternatively, the Subclass)

162. Plaintiff and the Class and Subclass incorporate by reference each allegation set forth in the preceding paragraphs, as if fully set forth.

163. Pleading in the alternative to an express warranty, Defendants have been unjustly enriched in that Defendants received the purchase or lease price of the Recalled Devices, a benefit which Defendants retained at the expense of Plaintiff and the Class and Subclass.

164. The benefit that Plaintiff and the Class and Subclass conferred on Defendants and that Defendants retained at the expense of Plaintiff and the Class and Subclass was the purchase or lease price of the Recalled Devices purchased or leased by Plaintiff and the Class and Subclass.

165. Defendants did not typically sell or lease their Recalled Devices directly to consumers or end users.

166. All Recalled Devices, including those purchased by Plaintiff, were sold by Defendants through approved distributors.

167. Plaintiff purchased his DreamStation devices from Horizon Sleep Medicine Services, Inc.

168. Plaintiff is informed and believes that Horizon Sleep Medicine Services, Inc. then paid Defendants, using Plaintiff's money, for the cost of the DreamStation devices.

169. On information and belief, Horizon Sleep Medicine Services, Inc. purchased the DreamStation devices it sold to Plaintiff from Defendants.

170. On information and belief, using Plaintiff's money, Horizon Sleep Medicine Services, Inc. paid Defendants for Plaintiff's DreamStation devices.

171. In this fashion, the benefit of Plaintiff's money, namely the purchase price of the DreamStation devices, was conferred on Defendants and retained by Defendants through the above described distribution channels for Plaintiff's DreamStation devices.

172. All of the Recalled Devices were sold to consumers or end-users in a similar manner to the above system, namely consumer or end-user pays the distributor who buys the Recalled Devices from Defendants.

173. Thus, Defendants were paid with Plaintiff's money indirectly through its distributor. The benefit of the purchase price was conferred on Defendants and retained at the expense of Plaintiff.

174. As between Plaintiff and Defendants, it is unjust for Defendants to retain the benefit conferred upon it by Plaintiff based upon the promises from Defendants that the DreamStation devices would be free from defects and be safe to use, none of which were delivered or fulfilled.

175. Defendants have been further unjustly enriched in that the price or lease paid by Plaintiff and Class and Subclass members for the Recalled Devices did not contemplate that consumers would bear the cost of replacing the defective Recalled Devices. At this time, Defendants have not provided an adequate replacement of the Recalled Devices or paid the cost of new machines. All such expenses conferred an unjust benefit on Defendants by virtue of Defendants

improperly shifting the burden of replacement costs to Plaintiff and members of the Class and Subclass.

176. Defendants have been unjustly enriched in that Plaintiff has expended $2468 to purchase a ResMed AirCurve 10 VAuto Bi-Level PAP machine to replace his defective DreamStation devices. As such, a benefit has been conferred upon Defendants and retained at Plaintiff's expense.

177. Plaintiff and the Class and Subclass members conferred a tangible and material economic benefit upon Defendants by purchasing or leasing the Recalled Devices. Plaintiff and Class and Subclass members would not have purchased, leased, chosen and/or paid for all or part of Recalled Devices had they known the true risks of using the Recalled Devices.

178. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiff and the Class and Subclass members who can no longer use their Recalled Devices safely.

179. Plaintiff and the Class and Subclass suffered damages equal to the purchase or lease price of the Recalled Devices, or the cost of replacing the machines and such other economic damages, the amount of which to be determined at trial.

180. As a direct and proximate result of their use of the Recalled Devices, Plaintiff and the Class and Subclass are at a substantially increased risk of developing serious medical conditions, including risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

181. The latent injuries from which Plaintiff, Class, and Subclass members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to harmful chemicals from the

degrading PE-PUR Foam and off-gassing VOCs, and is different from that normally recommended in the absence of exposure to this risk of harm.

182. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the aforementioned injuries.

183. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the aforementioned injuries.

184. By monitoring and testing Plaintiff, Class, and Subclass members, the risk that Plaintiff and the Class and Subclass members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

185. Plaintiff and the Class and Subclass members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the Class and Subclass members for the aforementioned injuries. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Class and Subclass members as frequently and appropriately as necessary.

186. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has used the Recalled Devices for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Class

and Subclass members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

187. Plaintiff and the Class and Subclass have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to use of the Recalled Devices. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the Class and Subclass members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly situated, prays the Court to certify the Class and Subclass as defined hereinabove, to enter judgment against Defendants and in favor of the Class and Subclass, and to award the following relief:

1. For certification of the proposed Class and Subclass thereof as may hereafter be alleged;

2. For the cost of replacement of the Recalled Devices;

3. For compensatory damages as alleged herein, according to proof;

4. For costs and attorneys' fees, as allowed by law;

5. For punitive damages;

6. For equitable relief in the form of a medical monitoring program to be funded by the Defendants;

7. For such other further legal or equitable relief as this Court may deem appropriate under the circumstances; and

8. In the alternative, Plaintiff prays to recover amounts that Defendants were was unjustly enriched, according to proof at trial.

JURY DEMAND

Plaintiff and the Class and Subclass demand a trial by jury on all issues so triable.

DATED: October 21, 2021

Respectfully submitted,

LEVIN SEDRAN BERMAN LLP

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